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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Nitenpyram Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The NADA provides for the oral use of nitenpyram tablets for the treatment of flea infestations in dogs, puppies, cats, and kittens that are 4 weeks of age and older and 2 pounds (lb) of body weight or greater.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed NADA 141–175 that provides for the over-the-counter use of CAPSTAR™ (nitenpyram) tablets for the oral treatment of flea infestations on dogs, puppies, cats, and kittens that are 4 weeks of age and older and 2 lb of body weight or greater. The NADA is approved as of October 20, 2000, and the regulations are amended in part 520 (21 CFR part 520) by adding § 520.1510 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support

approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning October 20, 2000, because no active ingredient (including any ester or salt of the drug) has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1510 is added to read as follows:

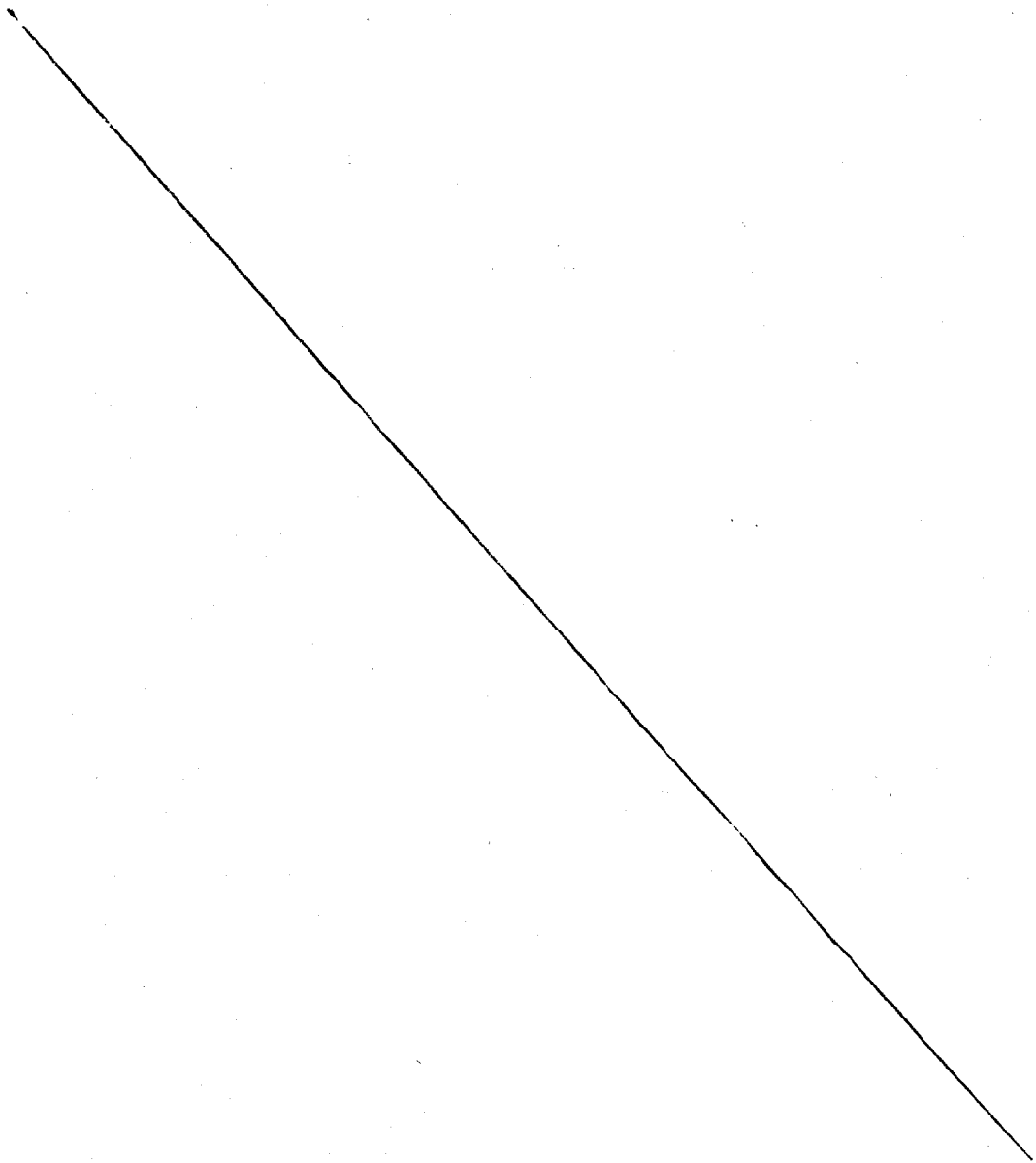
§ 520.1510 Nitenpyram.

(a) *Specifications*. Each tablet contains 11.4 or 57 milligrams of nitenpyram.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—Dogs and cats*—(1) *Amount*. One tablet given orally, as needed.



(2) *Indications for use*. For the treatment of flea infestations on dogs, puppies, cats, and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

Dated: 11/8/00

November 8, 2000

Stephen F. Sundlof
Director
Center for Veterinary Medicine

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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